K014058

DEC 21 2001

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

DEC 21 2001

## 10. 510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

**Date:** November 16, 2001

**Device Name**
**Proprietary Device Name:** eNTEGRA PE

**Establishment Name and Registration Number of Submitter**

| | |
|---|---|
| **Name:** | GE Medical Systems<br>3000 N. Grandview Blvd.<br>Waukesha, WI 53118 |
| **Registration Number:** | 2122726 |
| **Corresponding Official:** | D. Duersteler<br>Safety and Regulatory Project Engineer<br>GE Medical Systems EX-493<br>P.O. Box 414<br>Milwaukee, WI 53201<br>FAX 262-317-9190, Phone 262-317-9463 |

**Device Classification**

| | |
|---|---|
| **Classification Code:** | 90 LLZ |
| **Panel Identification:** | Radiology |
| **Classification Name:** | Picture Archiving and Communication System (per 21CFR 892.2050) |
| **Common Name:** | Nuclear Medicine Imaging Workstation |
| **Classification Class:** | Class II Product |

**Reason for 510(k) Submission**
Modification of legally marketed device.

**Identification of Legally Marketed Equivalent Devices**
eNTEGRA Processing and Review Workstation (*K000395*)

**Device Description and Intended Use of Device**
The eNTEGRA PE Diagnostic Imaging Personal Digital Assistant is a device intended to provide the same functionality as the eNTEGRA Workstation (cleared in 510(k) number K000395 as the "Einstein Processing And Review Workstation"). The eNTEGRA PE is different in that this functionality is implemented on a handheld personal computer or personal digital assistant (PDA). The eNTEGRA PE will extend the

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eNTEGRA P&R services to be utilized by the clinician while away from her office/desk.

The intended use of the device is to display, process, archive, and communicate data required and stored by Emission Tomography cameras and Nuclear Medicine/PET workstations.

**Summary of Studies**

Bench testing with representative sample images has concluded that the eNTEGRA PE system is fully functional and is operating as designed.

**Conclusion**

In the opinion of GE Medical Systems, the eNTEGRA PE system is substantially equivalent in terms of safety and effectiveness to the above mentioned legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2001

General Electric Medical Systems
% Mr. Reiner Krumme
Division Manager Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K014058
Trade/Device Name: eNTEGRA PE Personal Digital Assistant
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 5, 2001
Received: December 10, 2001

Dear Mr. Krumme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

## 9. Statement Of Intended Use

K014058

**Intended Use**

**eNTEGRA PE is designed to display, process, archive, and communicate data required and stored by Emission Tomography cameras and Nuclear Medicine/PET workstations.**

**It is intended that use of the device be limited to review of studies, tagging images for detailed reading, determining whether the correct images were captured, and similar uses.**

**The limited image size availble on eNTEGRA PE has not been fully demonstrated to be suitable for diagnostic use, and it is not intended to be used for direct diagnosis.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

David A. Legeman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014058